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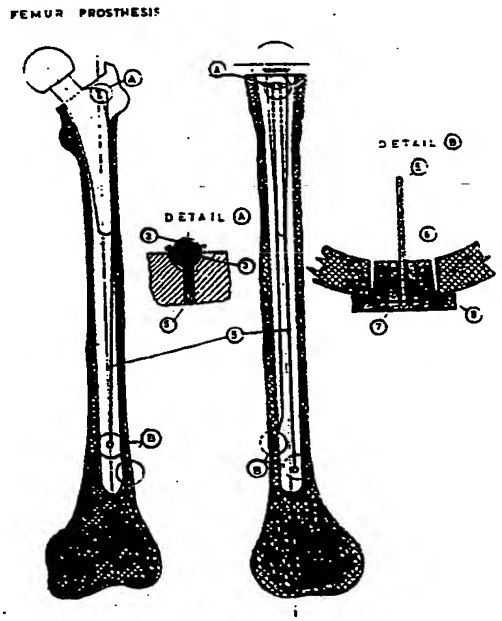
(54) Title: PROSTHESIS OF THE HIP- OR KNEE-JOINT ANCHORED WITH A PRESTRESSING ELEMENT

(57) Abstract

Prostheses of the hip and the knee joint, of which both components are anchored into the bone with prestressing tendons (5) and by interposition of a joint. The anchorage system of the prostheses for the femoral part of the hip joint prosthesis and for both parts of the knee joint prosthesis consists of:-(a) the sockets (3, 6) for the spheric end of the prestressing tendons on both components of the prostheses for the neutralization of tension forces, (b) the prestressing tendons, (c) the mechanism for bone protection, anchorage and fixing of the prestressing. The acetabulum part of the hip joint prosthesis is anchored into the bone of the pelvis with prestressing tendons.



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Prosthesis of the hip-or knee-joint anchored with a prestressing element.

As substitution for hip and knee joints, artificial joints (prostheses) have been in use, which were caulked in the bone with the help of bone cement. After a certain period of time, an aseptic loosening of both components of the hip as well as the knee joint prostheses is observed. This is due to the weakness of bone cement to cope with traction forces (mechanical weakness). To overcome this specific weakness, prostheses which do not use bone cement have been in use for a number of years.

Several attempts have also been made with modifications in the shape and the stem of the prostheses, which attempts aimed at the early charge and longer lifespan of the prostheses (main problems).

The suitable time to charge the artificial joint as well as its lifespan, depend on a number of factors, for example:

-The material and surface of the prosthesis.
-The joining between prosthesis and bone.
-The way of transfer of forces between prosthesis and bone.
-The spreading and uniform distribution of forces on the bone.
-The mechanical conditions created during the initial placing of the prostheses, to which the bone will adapt accordingly.

As opposed to the prostheses for which bone cement is used, cementless endoprostheses require the following: Biological harmonization between bone and prosthesis, and minimization of the consequenses caused by mechanical forces at points of contact between bone and prosthesis, so as to avoid or to reduce small movements between bone and prosthesis, which lead to loosening and rejection of the prosthesis. Moreover, the density of trabecular bone depends on the forces, which are received by the

bone. On artificial joints, a certain portion of the total forces are received by the prosthesis. This discharge of the trabecular bone leads to osteoporosis, which is another cause of loosening of the prosthesis.

The bone is capable of receiving great and continual pressure forces and adapt to them. In contrast, small, sudden and on a small area exercised pressure forces lead to excessive stress on the bone and to its atrophy. This results to bone absorption and loosening of the prosthesis.

The time needed for biological harmonization between prosthesis and bone is so shorter as smaller are the movements between prosthesis and bone. The lifespan of the artificial joints depends on the small movements between prosthesis and bone as well as on the osteoporosis caused by the discharge of the trabecular bone by the prosthesis.

The attempts made sofar concerned the stem of the prostheses. In the case of the hip joint, for example, (for the femur part of the prosthesis), the efforts were towards the creation of a counterbalancing traction zone. The prosthesis is loaded eccentrically with regard to the theoretical axis of the femur, creating a curving momentum, which affects the bone negatively, causing osteolysis, principally to the Adams arc and the femur diaphysis. Attempts of neutralization of this curving momentum with the use of screws from the prosthesis towards the area of the major trochanter have failed, because of the metal's weariness and breaking.

As for the stem of the prostheses in the case of the knee artificial joint, either plastic material has been placed on the extremity of the stem (attempt to diminish the small movements of the prosthesis), or the stem has been cut off alltogether.

During walking, the momentary and on part of the prosthesis exercised force is great and the only force that can compensate it, is a counter-force on the opposite part of the prosthesis. This eccentric force is

more effective if prestressing is used. The firmness of this prestressed force is achieved through the interposition of an articulating joint (one part of which is covered with plastic material) between the prosthesis and the prestressing bearer (commonly called `tendon´). This articulating joint receives the small movements, which continue, even diminished, to occur and prevents weariness and bending of the metal (it acts as a guide for the small movements).

The anchorage of the prestressing tendon as far away as possible from the prosthesis, causes pressure forces on the bone, which in turn cause osteogenesis. This anchorage is applied as peripherally as possible (Fig. I B) for the following two reasons: first because the pressure forces, which cause osteogenesis, are directed towards a greater part of the bone, and second because the difference in E-Module between the system prosthesis-prestressing tendon and the bone diminishes. The anchorage securing of the prestressing tendon is effectuated with the help of a washer (Fig. III 8), and the anchorage itself by the special cone (Fig.III 7). The outer part of the anchorage cone is used as a lever for the protection of the bone (Fig. III 6).

The application of prestressing is effectuated by means of wire tendons, made either of the same material as the prosthesis, or carbon fibres, or carbon fibre plastics. They have a diameter of I.2-I.8 mm and are of differing length and processing, depending on the way of application of prestressing, of adaptation to the joint and of anchorage within the bone. Their course is endomyelic (Fig. I) between the prosthesis and the lever for bone protection, and they are lying like tightened chords inside the femoral lumen.

For the neutralization of forces in the sagittal plane, the prestressing tendons are anchored frontally and laterally, dorsally and laterally respectively, as near to the knee joint as possible (Fig. I). With this anchorage technique of the prostheses in the bone we

achieve the following:

-The counterbalance of the pressure forces on the prosthesis by counterlateral traction forces on the prosthesis.

-The neutralization of the small movements of the prosthesis by the above mentioned counterlateral traction forces.

-The sufficiency of the traction forces on the prosthesis because of the application of prestressing.

-Bone osteogenesis because of the continual pressure forces on the bone, created by the application of prestressing.

-Minimization of the difference in E-Module between bone and prosthesis because of the application of prestressing on a large bone area.

Way of working.

-(Femoral prosthesis of the hip joint).

After the usual preparation of the femur to receive the prosthesis, on which the one end of the prestressing tendon is articulated, we introduce the other end of the tendon intramedularly through a plastic conducting tube to its anchorage place (lateral corticalis of the femur).

-(Acetabulum prosthesis of the hip joint).

The other part of the hip joint prosthesis, the acetabulum (Fig.VI), receives pressure forces on its ceiling and the small movements are neutralized or minimized whith the application of prestressing on the pubis, ischium and ilium. The acetabulum consists of two parts, the inner one, which is made of plastic material, with a spherical cavity for the formation of an articulation with the femur head of the prosthesis, and the outer part, made of metal, which is anchored into the bone of the pelvis with prestressing tendons and whose surface, which comes in contact with the bone, is of ellipsoidal shape for the enlargement of the area of distribution of forces. The anchorage in the pelvis, which is spongy, is effectuated with the special screws for anchorage into spongy bone (Fig.V I3). The screws are set with the

help of a flexible tap (Fig.V I2), which is guided forward within the spongy matter of the pelvis respecting the cortical bone, and are screwed with the help of the special screwdriver (Fig.V II).

The work is done as follows: A model acetabulum is applied on the preparated bone. This model bears guiding tubes towards the pubis, ischium and ilium, through which we place the anchorage screws of (Fig.V I3) with the help of the special, flexible screwdriver (Fig.V II), just under the bony surface. These screws serve as anchorage and at the same time as prestressing bearers. The other ends of these screws are accessible after the metal part of the double acetabulum is put in place. The prestressing is applied with the traction screws of (Fig. V I0) by screwing gradually and alternatively. The acetabulum serves as joint as well as resting point of the prestressing (i.e. the metal part of the double acetabulum). It serves as a joint (articulation) because the holes it bears for the traction screws form part of a concave sphere, whereas the base of the screws (Fig.V I0) are part of a sphere. This construction allows for small corrections and forms a joint at the same time.

The possibility of anchorage far away from the acetabulum, as well as the flexibility of the prestressing tendons and the existence of a joint between them and the acetabulum, secure solidity and elasticity for the system anonym bone-acetabulum, which allow early charge and a longer lifespan of the prosthesis.

-(Knee joint prosthesis).

As regards the knee joint prosthesis, both the femoral component as well as the tibial component receive pressure forces which are interchangeable, i.e. when the medial condyle of the prosthesis is under pressure, the lateral condyle of the prosthesis has the tendency to distance itself from its contact with the bony surface of the lateral condyle of the femoral bone. Because of this, traction (prestressed) forces have to be applied to both condyles. For the femoral condyles, the direction

of the prestressing application must be vertical to the plane created by the application of the prosthesis, and eventually, two or three prestressing tendons can be used for each condyle. The prestressing tendons cross each other and are anchored on the inferior third of the femoral bone. The bisector of the angle, which they form, must coincide with the axis of the femoral bone. The junction of the prestressing tendon with the prosthesis is done with a hook, which is part of a concave sphere, is by construction part of the prosthesis, and on which the sphere of the prestressing tendon is adapted. The tendons are anchored with the help of the distribution washer (Fig.III 8) and the lever for bone protection (Fig.III6), and the application of prestressing is achieved with dynamometers, and must be simultaneous and of the same tension for all prestressing tendons. They are finally anchored with the cone (Fig.III 7) or the traction screw (Fig.V IO).

In the case of the tibial condyles, we take into consideration the vertical to the plane formed by them, because of the inclination this plane has from upper frontally towards lower dorsally. This vertical does not follow the axis of the tibial bone but is in front of it and in this case, the intersection of the prestressing tendons must form an angle, whose bisector coincides with the axis of the tibial bone and is parallel to the above mentioned vertical. The knee joint prostheses have to be supplied with hooks (Fig.IV A) for the adaptation of the prestressing tendons, on the part of the prostheses, which receives the greatest traction forces. The prestressing tendons are anchored by the traction screw (Fig.V IO) or by the cone (Fig.III 7) and number from two to four.

For the knee joint, after the preparation of the condyles of the femur for the insertion of the prosthesis, two holes are made by means of a long drill, as follows: one is made from the medial condyle to the lateral hypercondylial surface of the femoral cortex, and the other is made from the lateral condyle to the medial femoral

cortex. Two prestressing tendons are introduced through these holes. After the prosthesis has been positioned by means of a hammer, and is perfectly in place, prestressing is applied with the help of two dynamometers simultaneously to both tendons, which are then anchored to the medial and lateral hypercondylial cortex either by means of the cone or the traction (prestressing) screw. We repeat the process for the tibial part of the prosthesis.

The lever for bone protection as well as the surfaces which are subject to contact and friction, are covered with hard plastic material.

The Material in use.

First of all, the prostheses must be fitted up with sockets to receive the sphere of the prestressing tendons on the appropriate place. For the femur head of the prosthesis, for example, these sockets are built on the opposite side of the head itself, on the place of the major trochanter, as eccentrically as possible, and if necessary, by modification of the shape of the prostheses. (The protrusion of this side of the prostheses like a double Z inside the mass of the major trochanter is desirable).

The prestressing tendons are separated according to their length, and are of specified and of unspecified length. The one end of the tendon of unspecified length forms a sphere for the creation of a joint with the socket on the prosthesis. Its other end is free, and after application of prestressing, is anchored within the bone through the cone.

Prestressing tendons of specified length are used in instances, where their exact length is known in advance. They have a length of 3 to 20 cm. The one end is cochleated (male screw), so that the traction (prestressing) screw (female screw) can be used, and the other end is either a sphere, so that they can adapt to the appropriate socket of the prosthesis, or it forms the head of a screw with wide spiral, suitable for anchoring into

spongy bone (Fig.V I3). (Eg. Acetabulum anchorage). These screws are very short, 5-8mm, and have a hole in the centre for the appropriate screwdriver (Fig.V II). They are put in place with the help of the special tap (Fig. V I2), which has the shape of a rounded, truncated cone, and has at its base a short articulated cutter mill for the use of the screwdriver. This screwdriver is short and flexible, with a central opening as receptor for the prestressing tendon.

The outer part of the anchorage cone (Fig.III) forms a joint with the washer and is used as a lever for bone protection. The traction (prestressing) screw (Fig.V I0) can be put instead of the cone inside the above mentioned outer part of the cone, and forms a joint with the washer.

With the above described way of anchorage of the prostheses, i.e. with prestressing and interposition of a joint at the points of anchorage and fixing of the prestressing tendons, we achieve stability and elasticity for the whole system prosthesis-prestressing tendons-bone, which ensure the early charge and a longer lifespan of the prostheses by the creation of ideal mechanical conditions, and ameliorate the walking quality.

C L A I M S

I. Prostheses of the hip joint and the knee joint, of which both components are anchored into the bone with prestressing tendons and by interposition of a joint.

The anchorage system of the prostheses for the femoral part of the hip joint prosthesis and for both parts of the knee joint prosthesis consists of: a) the sockets for the spheric end of the prestressing tendons on both components of the prostheses for the neutralization of tension forces, b) the prestressing tendons, c) the mechanism for bone protection, anchorage and fixing of the prestressing.

The acetabulum part of the hip joint prosthesis consists of two parts, the inner one, which is made of plastic material, with a spherical cavity for the formation of an articulation with the femur head of the prosthesis, and the outer part, made of metal, which is anchored into the bone of the pelvis whith prestressing tendons and its surface, which comes in contact with the bone, is of ellipsoidal shape for the enlargement of the area of distribution of forces.

2. Prostheses of the hip joint and the knee joint, according to claim I, whose components bear sockets, which are either cavities, or openings, or hooks, all of hemispherical shape, for the housing and anchorage of the spheric end of the prestressing tendons, which form articulations inside the sockets.(Figures I,II,IV,VI).

3. Prostheses of the knee joint, according to claim I, whose both components, the femoral as well as the tibial, bear 2-4 sockets for the articulated anchorage of the prestressing tendons. The other end of the prestressing tendons is anchored in the bone cortex far away from the prosthesis, into the mechanism for bone protection and for anchorage.(Fig.IV).

4. The tendons for the application of prestressing, according to claim I, are thin metal wires, or branchy wire (in which case they are covered with plastic material), or other materials with the same mechanical properties (carbon fibres or carbon fibre plastics,e.t.c.). Their one end either forms a sphere for their articulated anchorage into the appropriate sockets of the prostheses, or is adjusted to the head of the anchorage screw with wide spiral, suitable for anchoring into spongy bone, in which case their other end forms an external screw for the traction screw. (Figures II,V).

5. The mechanism for bone protection, anchorage and fixing of the prestressing, according to claim I, consists of: a) the fulcrum for bone protection, cylindrical body with a conical cavity for the anchorage of the prestressing tendons through a cone, whose base is of semicircular cross-section for the formation of a joint with the washer, and b) the washer for fixing of the prestressing and distribution of forces, whose side coming in contact with the bone has a concave or a convex shape depending on the bone surface and bears small dents, and whose aperture is of semicircular cross-section for the formation of an articulation with the base of the fulcrum for bone protection.(Figures I,III,VI).

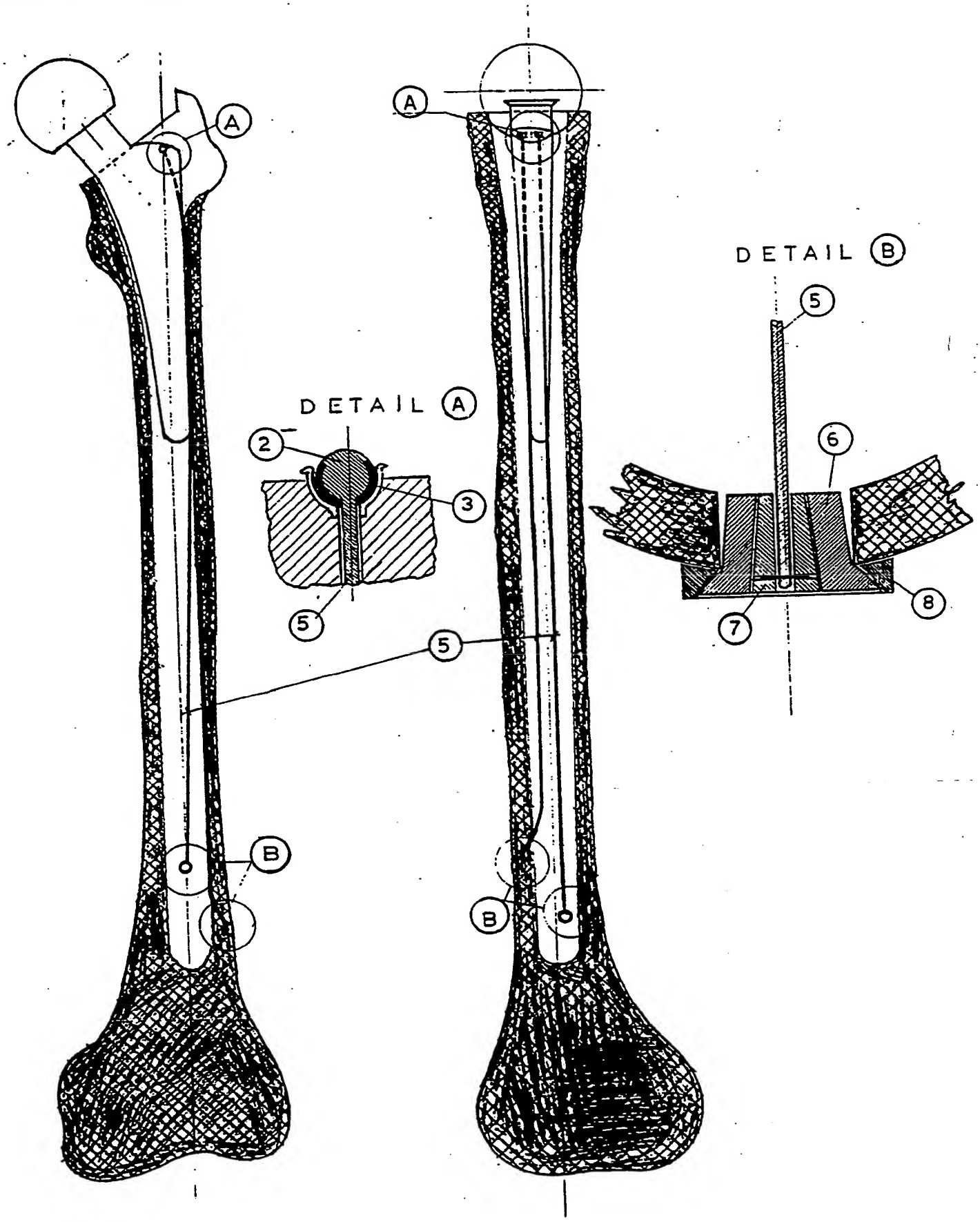
6. The acetabulum part of the hip joint prosthesis, according to claim I, consists of two parts, the metallic one (outer part) and the plastic one (inner part). The metallic part is of ellipsoidal shape as concerns its surface which comes in contact with the bone acetabulum, and of hemispherical shape as concerns its surface which comes in contact with the plastic part of the acetabulum, and bears openings of hemispherical cross-section for the articulated anchorage of the prestressing tendons. (Figure VI).

7. Anchorage screw, according to claim 4, which is fit for the anchorage into spongy bone. It has the shape of a rounded, truncated cone so as to avoid piercing the cortical bone. It bears the prestressing tendon and the housing of the appropriate screwdriver at its head. For its screwing we use a special flexible tap, which also respects the cortical bone and a special flexible screwdriver. This screwdriver has a central opening as receptor for the prestressing tendon. (Figure V).

8. The application and fixing of the prestressing are effectuated with the help of the traction (female) screw, which is screwed around the prestressing tendon (male screw), and whose head forms an articulation with the metallic part of the acetabulum prosthesis.(Figures V,VI).

FIGURE I

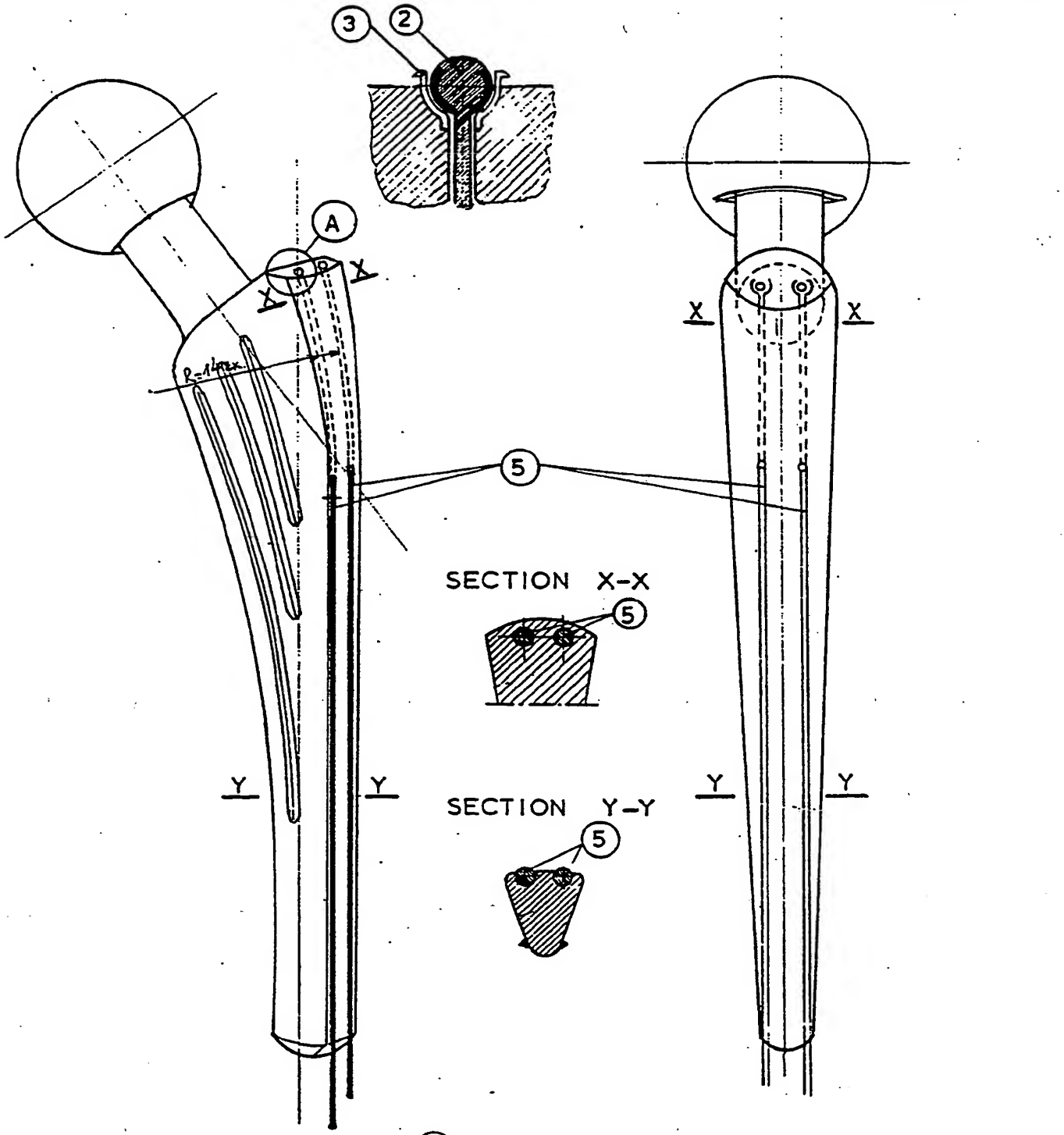
FEMUR PROSTHESIS



FEMUR PROSTHESIS

DETAIL A

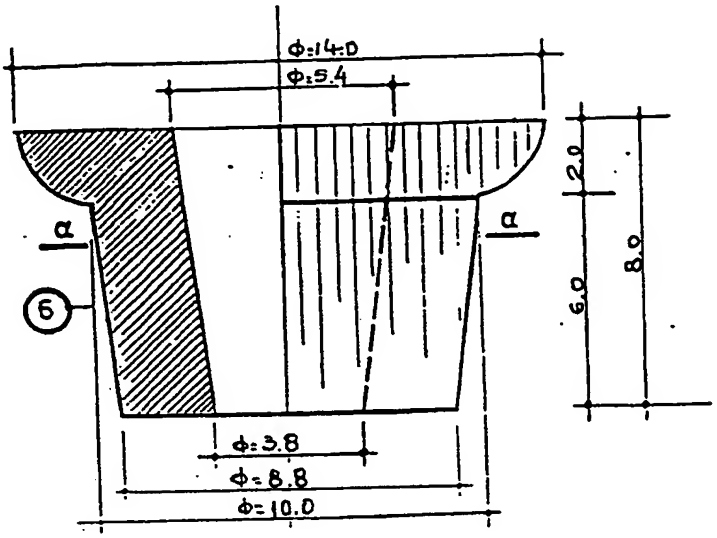
FIGURE II

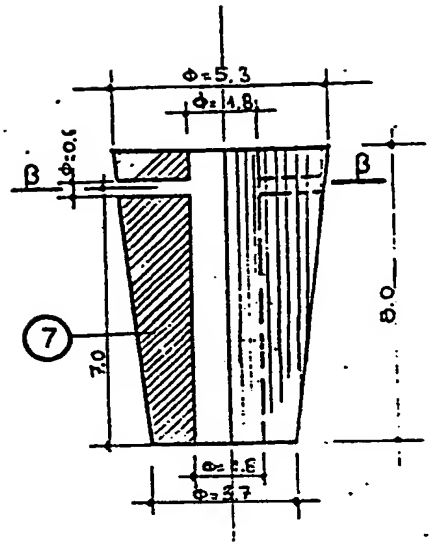


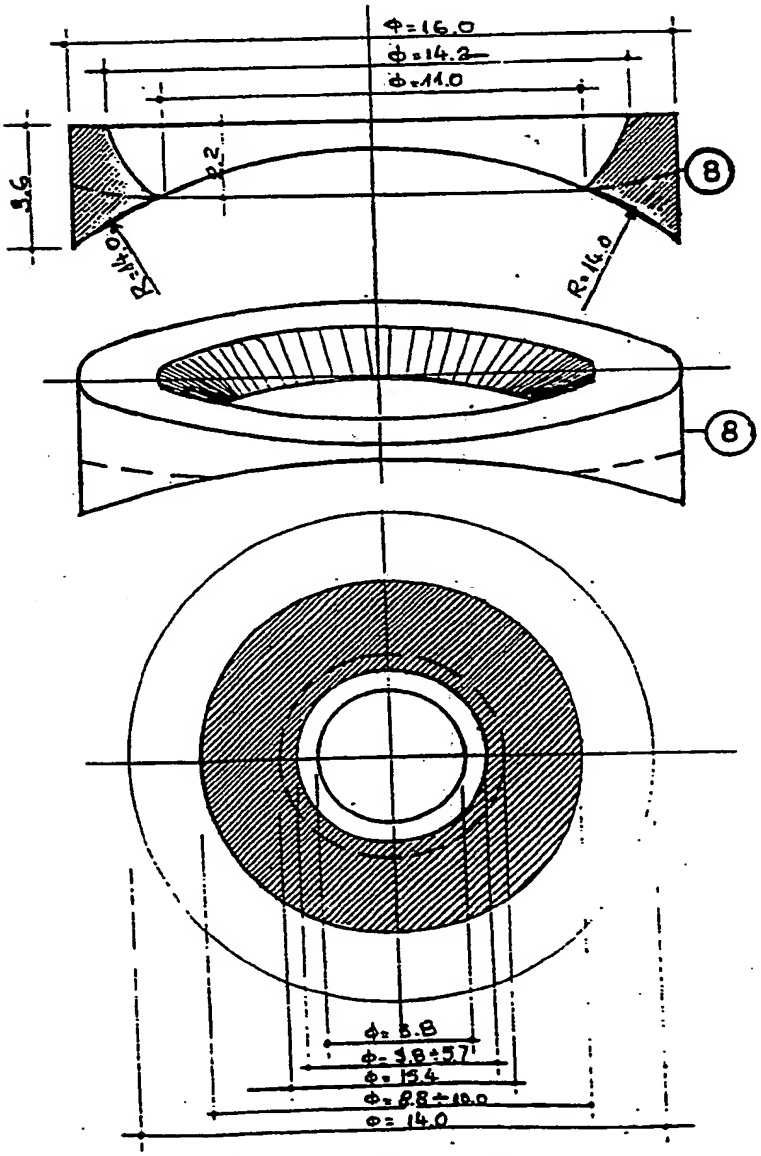
(2) spheric head of prestressing tendon
(3) metal socket
(5) prestressing tendon

MECHANISM FOR ANCHORAGE AND BONE PROTECTION

FIGURE III

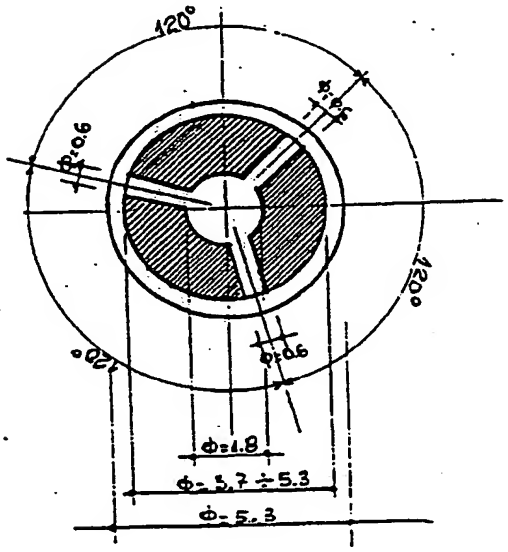






SECTION α-α

SECTION β-β



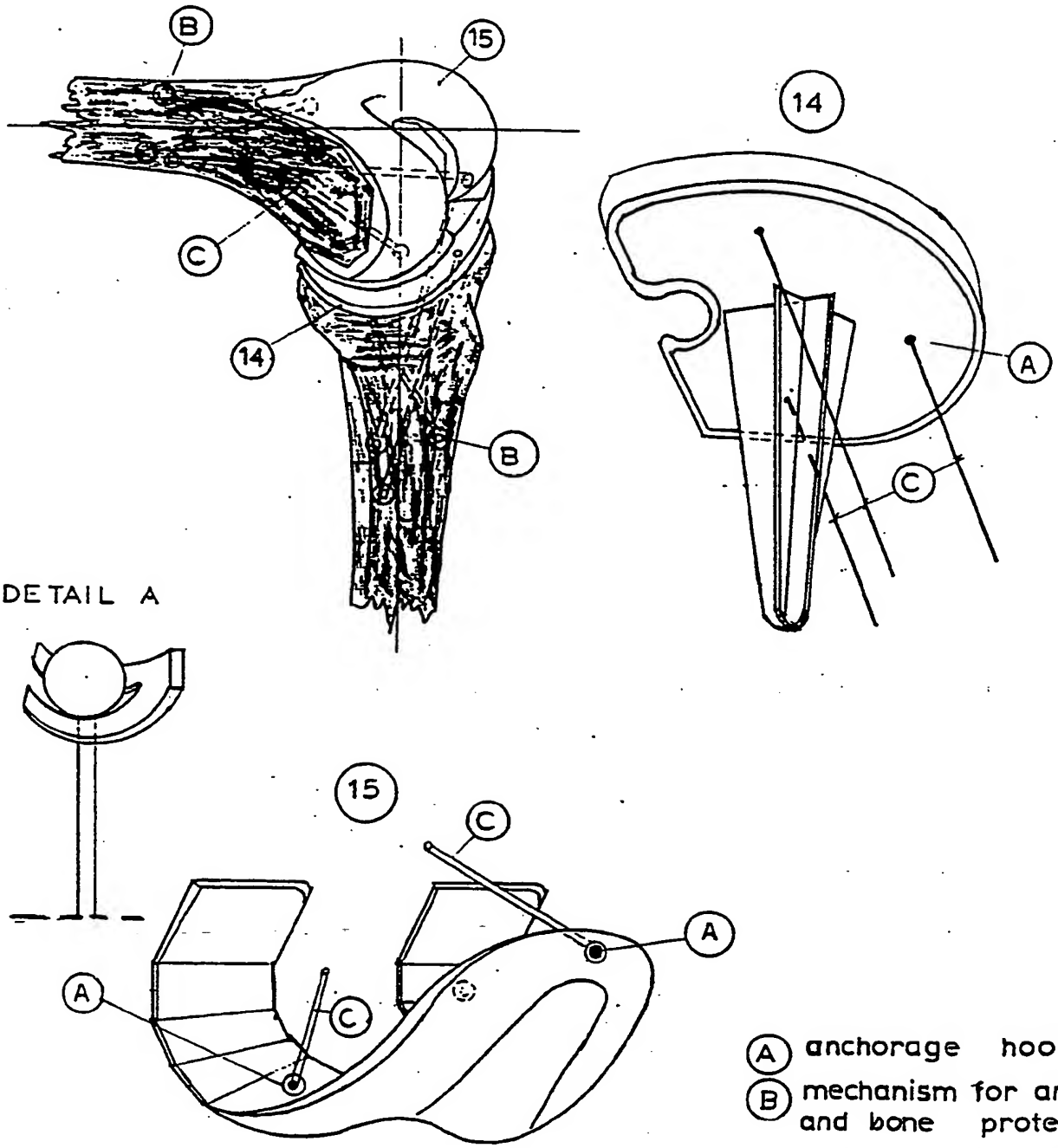
6 Lever for bone protection

7 Anchorage cone

8 Washer

KNEE JOINT PROSTHESIS

FIGURE IV



(A) anchorage hook

(B) mechanism for anchorage and bone protection

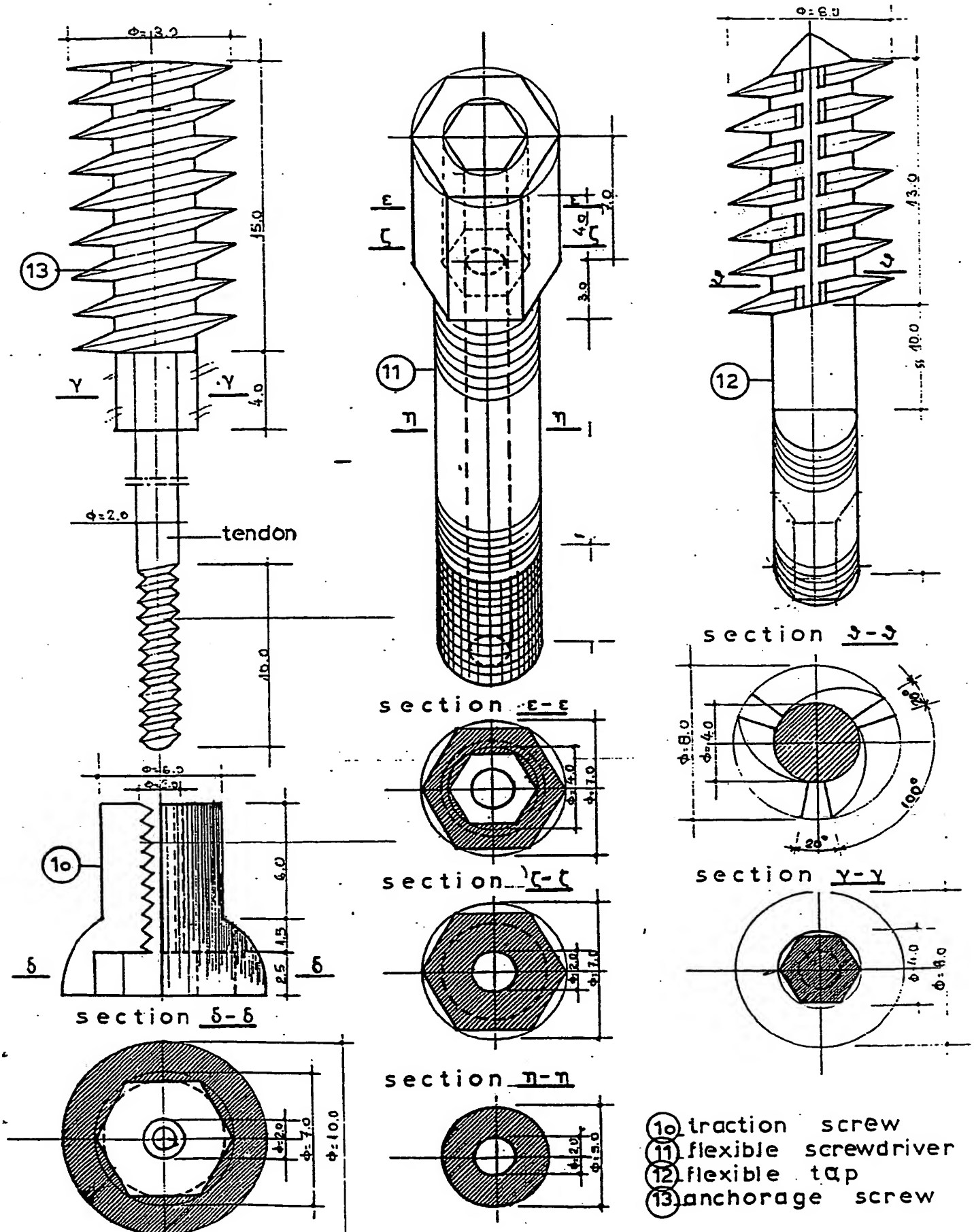
(C) prestressing tendon

(14) TIBIAL PART OF KNEE PROSTHESIS

(15) FEMUR PART OF KNEE PROSTHESIS

NEW

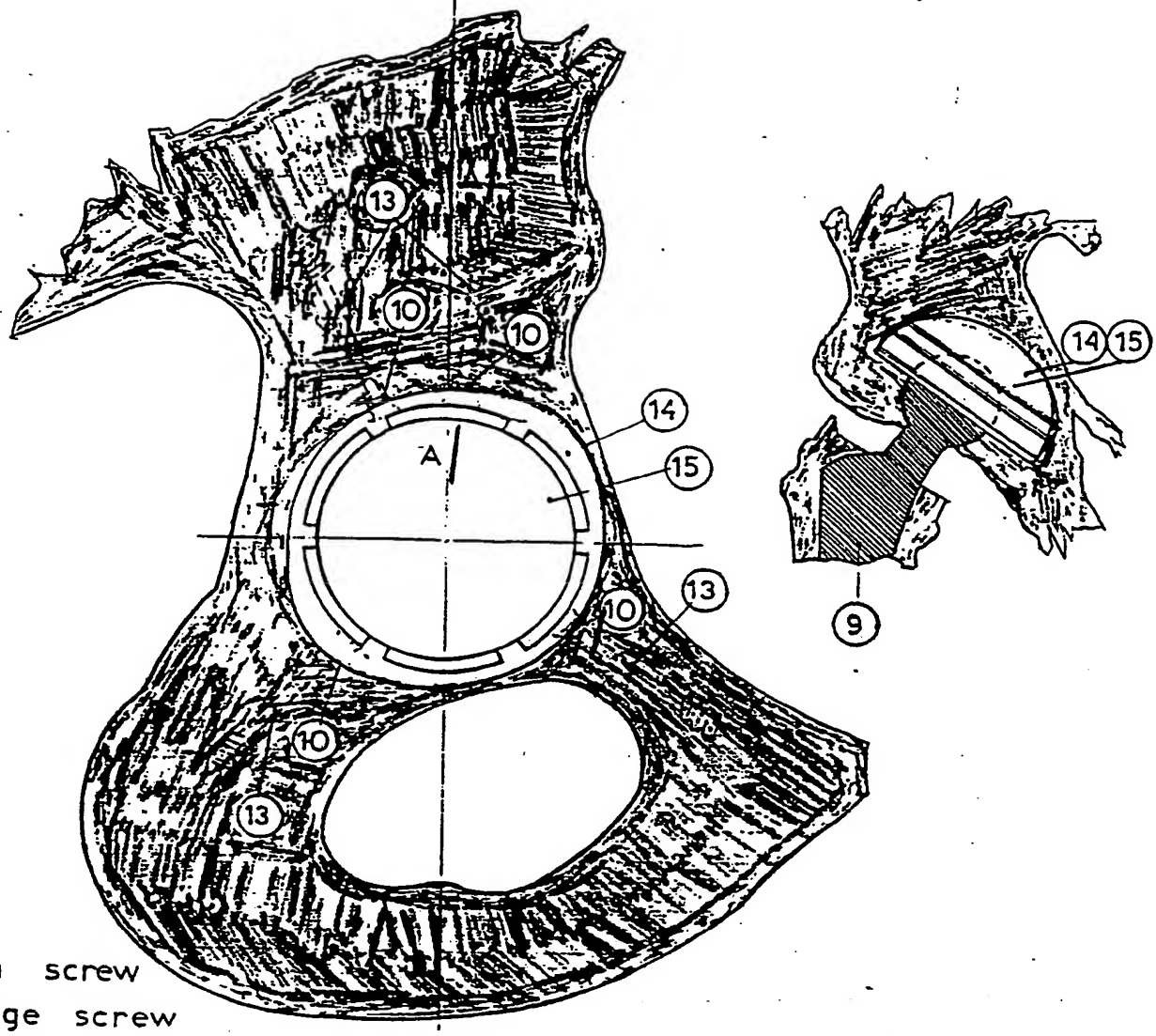
FIGURE V



10 traction screw
11 flexible screwdriver
12 flexible tap
13 anchorage screw

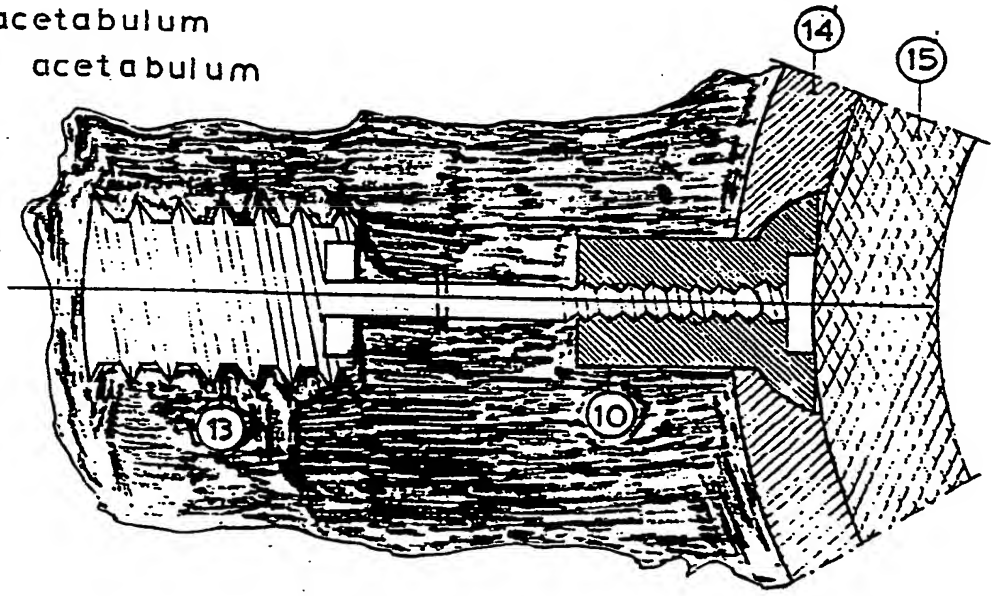
FIGURE VI

ACETABULUM PROSTHESIS



(10) traction screw
(13) anchorage screw
(14) metal part of acetabulum
(15) plastic part of acetabulum

SECTION A-A



INTERNATIONAL SEARCH REPORT

International Application No PCT/GR 90/00006

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[5]: A 61 F 2/32, A 61 F 2/38, A 61 B 17/58, F 16 B 35/04

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[5]	A 61 F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 4080666 (FIXEL) 28 March 1978 see column 2, lines 9-19; figures --	1
A	WO, A, 89/00414 (MATTHECK) 26 January 1989 see abstract; figures --	1-4
A	WO, A, 86/04808 (MARTIN) 28 August 1986 see figures; page 10, lines 1-21 --	
A	EP, A, 0163121 (WALDERMAR LINK) 4 December 1985 see figure 7; page 10, lines 2-11 -- ./.	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
30th January 1991	21. 02. 91
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	Natalie Weinberg

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Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	FR, A, 2184159 (TEINTURIER) 21 December 1973 see the whole document --	
A	US, A, 4456005 (LICHTY) 26 June 1984 see abstract; figures --	
A	FR, A, 2406433 (OH) 18 May 1979 --	
A	EP, A, 0243298 (MECRON) 28 October 1987 --	
A	EP, A, 0134406 (WALDEMAR LINK) 20 March 1985 ----------	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GR 9000006 SA 41481

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 11/02/91
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